

**UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF NORTH CAROLINA  
CHARLOTTE DIVISION  
CIVIL ACTION NO. 3:09 CV 210-RJC-DSC**

**MARY CLEO COUICK,**

**Plaintiffs,**

**v.**

**WYETH, INC., ACTAVIS INC.,**

**ACTAVIS ELIZABETH, LLC,**

**SCHWARZ PHARMA, INC., and**

**PLIVA USA, INC.,**

**Defendants.**

**MEMORANDUM AND RECOMMENDATION**

**THIS MATTER** is before the Court on “Defendant PLIVA, Inc.’s Motion for Judgment on the Pleadings Based upon Federal Preemption” (document #35) filed November 4, 2009; and “Plaintiff’s Response ...” (document #38).

This matter has been referred to the undersigned Magistrate Judge pursuant to 28 U.S.C. § 636(b)(1)(B), and this Motion is now ripe for the Court’s consideration.

The facts relevant to this dispositive Motion are straightforward. Plaintiff alleges that between July 2002 and April 2007, her physician prescribed Reglan, manufactured by the “brand name Defendants” Wyeth Inc. and Schwarz Pharma, Inc., or metoclopramide, a generic bioequivalent of Reglan manufactured by the “generic Defendants” Actavis Inc./Actavis-Elizabeth LLC (hereinafter “Actavis”) and Pliva USA, Inc., to treat her reflex esophagitis. Plaintiff further alleges that overexposure to those medicines caused her to develop tardive dyskinesia.

On May 28, 2009, Plaintiff filed her Complaint, which includes claims against the generic Defendants under state law tort theories of negligence, breach of undertaking special duty,

misrepresentation, infliction of emotional distress, unfair trade practices, breach of warranties, fraud, and failure to warn. In their briefs, the parties agree that the essence of Plaintiff's claims against the generic Defendants is inadequate warning. Plaintiff contends that the generic Defendants' labeling should have included stronger warnings about the association between long-term exposure to metoclopramide and movement disorders such as tardive dyskinesia.

As Plaintiff points out in her response, Defendant PLIVA's Motion for Judgment on the Pleadings presents the same question raised in Defendants Actavis' "Motion to Dismiss" (document #12) filed August 24, 2009. Defendant Actavis contended that because the federal statutory and regulatory scheme administered by the Federal Drug Administration ("FDA"), see Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j); 21 C.F.R. § 314.150., requires generic drug manufacturers to label their product identically to the brand name drug, Plaintiff's state law claims against the generic Defendants are conflict-preempted. Defendant PLIVA now makes that same argument.

On September 30, 2009, the undersigned respectfully recommended to the District Judge to whom this case is assigned (the Honorable Robert J. Conrad, Jr.) that Defendant Actavis' Motion to Dismiss be denied. See "Memorandum and Recommendation" (document #26) (Supreme Court's recent ruling in Wyeth v. Levine, 129 S.Ct. 1187, 1204 (2009), which held that state law failure-to-warn claims against the brand name manufacturer of an anti-nausea medication are not preempted by federal law, applies to generic drug manufacturers as well). Document #26 at 6.

For the same reasons, and having again fully considered the arguments, the record, and the applicable authority, the undersigned respectfully recommends that Defendant PLIVA's Motion for Judgment on the Pleadings be denied.

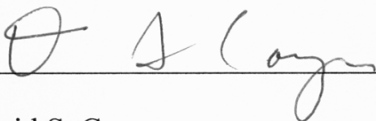
### **NOTICE OF APPEAL RIGHTS**

The parties are hereby advised that, pursuant to 28 U.S.C. §636(b)(1)(c), written objections to the proposed findings of fact and conclusions of law and the recommendation contained in this Memorandum must be filed within ten (10) days after service of same. Page v. Lee, 337 F.3d 411, 416 n.3 (4th Cir. 2003); Snyder v. Ridenour, 889 F.2d 1363, 1365 (4th Cir. 1989); United States v. Rice, 741 F. Supp. 101, 102 (W.D.N.C. 1990). Failure to file objections to this Memorandum with the District Court constitutes a waiver of the right to de novo review by the District Court. Diamond v. Colonial Life, 416 F.3d 310, 315-16 (4th Cir. 2005); Wells v. Shriners Hosp., 109 F.3d 198, 201 (4th Cir. 1997); Snyder, 889 F.2d at 1365. Moreover, failure to file timely objections will also preclude the parties from raising such objections on appeal. Diamond, 416 F.3d at 316; Wells, 109 F.3d at 201; Page, 337 F.3d at 416 n.3; Thomas v. Arn, 474 U.S. 140, 147 (1985); Wright v. Collins, 766 F.2d 841, 845-46 (4th Cir. 1985); United States v. Schronce, 727 F.2d 91 (4th Cir. 1984).

The Clerk is directed to send copies of this Memorandum and Recommendation to counsel for the parties; and to the Honorable Robert J. Conrad, Jr.

**SO RECOMMENDED AND ORDERED .**

Signed: November 24, 2009



David S. Cayer  
United States Magistrate Judge

